510(k) Summary of Safety and Effectiveness

K093410

SUBMITTER:	Surgical Devices, a global business unit of Tyco Healthcare Group LP (d/b/a Covidien) 60 Middletown Avenue North Haven, CT 06473 Tel. No.: (203) 492-5352
CONTACT PERSON:	Frank Gianelli Senior Associate, Regulatory Affairs
DATE PREPARED:	October 29, 2009
TRADE/PROPRIETARY NAME:	Autosuture™ Endo GIA™ Staplers
COMMON/USUAL NAME:	Surgical Stapler with Implantable Staples
CLASSIFICATION NAME:	Staples, Implantable
PREDICATE DEVICE(S):	Autosuture™ Endo GIA™ Stapler (K083519; K061095)
DEVICE DESCRIPTION:	This 510(k) shall describe a new Reload cartridge with Tri-Staple™ technology for use with the currently marketed Autosuture™ Endo GIA™ Stapler as described in the predicate submission K083519. The black Reload bears the identical design characteristics as the Reloads with Tri-Staple™ Technology described in the predicate submission with the exception that the staples sizes shall be 4.0, 4.5, and 5.0 mm for use in extra thick tissue. The black Reloads shall be made available in 45 mm and 60 mm lengths.
INTENDED USE:	The Autosuture™ Endo GIA™ Staplers have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection, and creation of anastomoses. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures. Note: The Autosuture™ Endo GIA™ Single Use Black Reload with Tri-Staple™ Technology is intended for use with the Autosuture™ Endo GIA™ Stapler and does not carry a separate indication from the stapling device.
TECHNOLOGICAL CHARACTERISTICS:	The Endo GIA™ Single Use Black Reload with Tri-Staple™ Technology for use in extra thick tissue is substantially equivalent to the predicate Reload cartridges with regard to the stapling technologies employed. The addition of the Single Use Black Reload with Tri-Staple™ Technology provides an additional offering to the surgeon where thick tissue must be transected or resected.
MATERIALS:	All components of the Autosuture™ Endo GIA™ Single Use Black Reload with Tri-Staple™ Technology are comprised of materials that are in accordance with ISO Standard 10993-1.
PERFORMANCE DATA:	Bench and in-vivo performance evaluations were conducted to demonstate that the new Endo GIA™ Single Use Black Reload with Tri-Staple™ Technology when used with the Autosuture™ Endo GIA™ Stapler is safe and effective and performs as intended.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Surgical Devices
Tyco Healthcare Group LP
(d/b/a Covidien)
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K093410
Trade/Device Name: Autosuture™ Endo GIA™ Single Use Black Reload with Tri-Staple™ Technology
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW
Dated: October 30, 2009
Received: November 2, 2009

Dear Mr. Gianelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K093410

Device Name: Autosuture™ Endo GIA™ Single Use Black Reload with Tri-Staple™ Technology

Indications For Use:

The Autosuture™ Endo GIA™ Staplers with Endo GIA™ Single Use Reloads have applications in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093410